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1654

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1654
KNUDSEN, et al.	)	Examiner: TELLER, Roy
Serial No.: 09/987,108	)	Washington, D.C.
Filed: November 13, 2001	)	October 9, 2003
For: BIOSENSOR	)	Docket No.: KNUDSEN=1A
	)	Confirmation No.: 6445

ELECTION WITH TRAVERSE

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S i r :

1. In response to the restriction requirement mailed September 9, 2003, Applicant hereby makes the following elections, all with traverse:

- Group II (claims 45-69)
- SEQ ID NO:1 (Bos taurus) from claims 4 and 34
- Lys-50 from claims 12 and 42
- acrylodan (fluorescent moiety) from claims 30 and 32.

2. The Examiner characterizes the groups as "unrelated". Inventions are "related" if they are not "independent", i.e., there is some "disclosed relation there between". See MPEP 806 and 806.04(b); MPEP 803, under "Distinct", says that "the term related is used as an alternative for dependent". MPEP 802.01 explains that for inventions to be considered independent, they must be "unconnected in design, operation or effect". It also gives as examples of related inventions, e.g., "process and apparatus for its practice" and "process and product made".

Here, there is clearly a relationship among at least groups

I-III. The construct of group II could be used as the "binding construct" in the method of group I (a relationship of product-to-method of use, see MPEP 806.05(h)), and the kit of group III comprises the construct of group II (a relationship of combination-to-subcombination, see MPEP 806.05(a)-(c)).

We have amended claim 1 to explicitly require the construct of claim 26, and hence the relationship between I and II is now not merely disclosed, but claimed.

Group IV relates to a method of determining free fatty acids in a sample. The construct of group II binds a hydrophobic coenzyme A ester. The construct of group II can be used in the quantitative analysis contemplated by group IV. See page 8, lines 17-30, and claim 65. We have amended its base claim 60 to refer to the construct of claim 26.

Given the relatedness of group II to groups I and III, and more distantly, group IV, the Examiner erred by characterizing them as unrelated (independent) inventions.

Admittedly, related inventions can be restricted if (1) they are distinct as claimed, and (2) it would be a serious burden on the Examiner not to require restriction. See MPEP 803 (Criteria") and 806.01. However, the instant restriction requirement contains neither distinctness nor burden analysis and hence is fatally inadequate to justify restriction.

We take this opportunity to point out that even if a <u>prima facie</u> case for restriction is established, if the claims of group II are found to be patentable over the prior art, the dependent claims of group I are properly rejoined under MPEP 821.04.

We also wish to point out that with regard to the II/III restriction, that under MPEP 806.05(c), restriction between combination and subcombination is proper only if "two-way obviousness" is shown.

3. The Examiner further requires us to

select **one** SEQ ID NO:1-30 from claims 4 and 34

select **one** amino acid from claims 12 and 42.

The office action is fatally ambiguous as to whether this is a restriction requirement under 37 CFR 1.142 or an election of species requirement under 37 CFR 1.146. The distinction is significant because an election of species requirement is withdrawn if a generic claim is deemed allowable, see MPEP 809.02(c)(B)(1).

On page 2, lines 3 and 4 from the bottom, the requirement is prefaced by "This application also contains claims directed to the following patentably distinct species of the claimed invention", which implies that the action is taken under 37 CRF 1.146. On the other hand, on page 3, line 1 the Examiner states, "Applicant is advised that this is a restriction and not an election of species". That implies that the action is a restriction under 37 CFR 1.142.

Muddying the issue further, in the second-to-last paragraph on page 3, the Examiner alludes to the requirement to select a sequence:

> Should applicant traverse on the grounds that the sequences are not patentably distinct, applicant should submit or identify such evidence now of record showing the sequences to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103(a) of the prior invention.

This language is plainly based on election-of-species practice, in which traditionally a species restriction could be traversed based on an express admission that the species were not patentably distinct, at the risk that, if one species was in the prior art, the admission could be used in a rejection of the others.

4. The ambiguity of the action is sufficient basis for traversal. However, to expedite prosecution, we further traverse the requirement on the ground that if restriction under 37 CFR 1.142 was intended, the Examiner has failed to make out a prima facie case that the sequences and the recited Cys substitution sites define "independent and distinct inventions".

SEQ ID NOS:1-30 are the sequence of acyl-coenzyme A binding proteins from various species. These sequences are plainly related by their common enzymatic activity, as well as structurally by the homology depicted in Figure 1. Plainly, they are not independent. Is it the Examiner's position that these sequences are all patentably distinct from each other? If so, he should say so explicitly. Also, he should show that it would be a serious burden to search them all.

In this regard, the Examiner's attention is respectfully directed to page 14, line 24 to page 15, line 2.

With regard to the mutations set forth in claim 12, in each case an identified residue of bovine ACBP is being replaced by a cysteine. The purpose of this is to provide a functionality for binding the signal moiety, see page 15, lines 26-28. The only significance of the location appears to be that the substitution not perturb the enzymatic activity of the protein. Again, there is a common function (linking the signal moiety) and structure (all mutations result in a cysteine substitution and the mutated proteins are all over 90% identical to each other), so these are related inventions. Again, the Examiner has not made out a prima facie case of distinctness or burdensomeness.

5. We further believe it appropriate to point out that we have not separately claimed the sequences of claim 4 or the Cys substitution sites of claim 12.

Rather, they are recited within Markush groups. Hence, the restriction is further traversed on the basis of MPEP 803.02 ("Restriction - Markush claims), i.e., "the members of the

Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions".

6. If the Examiner in fact intended to make an "election of species" requirement, then we traverse on the ground that a generic claim is allowable. (This applies also to the unambiguous requirement for electing a species of "fluorescent moiety".)

Respectfully submitted,

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